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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,383

08/21/2003

Vincent G. Copa

AMS0008/US

9726

33072

7590

03/08/2007

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/646,383

Applicant(s)

COPA ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 18 December 2006.
The examiner acknowledges the corrections made to the claims and the specification.
The examiner also withdraws the objections made to the claims after receiving clarification from the applicant.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 7-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bander** (U.S. Patent No. **6,299,598**) in view of **Seiba** (U.S. Pub. No. **20030229364**).

Claims 1-3, 7-10, and 12-14: **Bander** discloses a hollow, elongate, flexible catheter body **10** having a proximal end and a distal end, an inflatable balloon **24** at the distal end, and a drainage lumen (Figure 4 and col. 3, lines 32-40). **Bander** discloses the claimed device except for a tissue approximating structure, or means, on the catheter body on a proximal side of the balloon at a location to contact severed tissue.

Seiba teaches a tissue approximating structure **200** with multiple, opposing tines on a catheter body **220** on a proximal side of a balloon **240**, and is beneficial during anastomosis in a radical retropubic prostatectomy to engage the urethra and bladder

and facilitate fluid flow and patency of the two conduits (Figure 9B and page 2, paragraph 25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue approximating structure, as taught by Seiba, to Bander in order to make the device applicable to anastomosis using a device that facilitates fluid flow and patency of the two conduits.

3. Claims 4-6, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bander** (U.S. Patent No. **6,299,598**) and **Seiba** (U.S. Pub. No. **20030229364**), as applied to Claims 1,3, and 9 above, and further in view of **Biggs et al.** (U.S. Patent No. **6,599,311**).

Claims 4-6, 11 and 14: Bander and Seiba disclose the claimed device, including an inflation lumen extending from the proximal end to the balloon (Bander, col. 4, lines 17-21), a drainage lumen connected to the distal end extending from a drainage aperture **14** at the distal end to a drainage port **16** at the proximal end (Bander, col. 3, lines 32-40), and both distal and proximal, movable elongate tines (Seiba, Figure 9B), except for the tines being positioned to extend through apertures in the hollow catheter body and an actuating mechanism that is connected to the tissue approximating means that can be extended and retracted from apertures in the catheter body, and the actuating mechanism extends through a lumen along a portion of the length of the device to the proximal end which actuates the tissue approximating means.

Biggs et al. teaches tines **266** being positioned to extend through apertures **264** in a hollow body catheter **260** (Fig 31B and col. 20, lines 1-7). Biggs et al. also teaches

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an actuating mechanism **202** that is connected to a tissue approximating means **204** that can be extended and retracted from apertures in the catheter body, and the actuating mechanism may extend through a lumen along a portion of the length of the device to the proximal end which actuates the tissue approximating means (Figures 24A-24B, col. 19 lines 1-10). Biggs et al. teaches that this mechanism allows for the anchoring device to be advanced into a passageway in a non-extended form until it reaches a position where it can be attached to tissue and may subsequently be extended through the apertures (col. 2, lines 62-67 and col. 3, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide extendable tines through apertures in a hollow catheter and an actuating mechanism that is connected to and actuates the tissue approximating means, as taught by Biggs et al., to Bander and Seiba in order to move the catheter, or the device within the catheter, without being engaged to the tissue until it is at a desired location at which point the tines can be extended.

Response to Arguments

4. Applicant's arguments filed 18 December 2006 have been fully considered but they are not persuasive.

5. The applicant generally argues that combining the tissue approximating structure of Seiba to the catheter of primary reference of Bander would not result in the tissue approximating structure being on a *proximal* side of the catheter balloon of Bander, as claimed, but rather on the distal side of the catheter in order to be at a useful location on

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the Bander catheter. The examiner disagrees. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue approximating structure proximal either of the catheter balloons **24** and **25**, as seen in Figure 4 of Bander in order for retention of the device and to facilitate fluid flow and patency. Although the applicant recites the tissue approximating structure being on the *proximal* of the catheter balloon, the essence of the invention requires that the tissue approximating structure be on the side *opposite* of the boundary of the bladder, which happens to be on the distal side of the balloon in Bander.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER